

Applicants: Lawrence G. Lum and Randall J. Lee
Serial No.: 10/553,853
Filed: October 19, 2005
Page 4

REMARKS

Claims 1-12, 17, 24, 25, 46, 62, 65 and 89 are pending in the subject application. Applicants have hereinabove amended claims 1, 9, 11 and 46, added new claim 92, and canceled claims 2-8, 10, 12, 17, 24, 25, 62, 65 and 89 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future. Support for the amendments to the claims can be found in the specification, *inter alia*, as follows: claim 1: Page 30, lines 29-32; Project 3 on page 36, line 23 to page 38, line 7; claim 9: page 12, lines 15-16 and page 18, lines 27-30; claim 46: page 16, lines 21-27; Project 3 on page 36, line 23 to page 38, line 7. Support for new claim 92 can be found in the specification, *inter alia*, at page 35 line 32 to page 36, line 3. Upon entry of this amendment, claims 1 and 9 and 11 will be pending and under examination.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 1-12 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent Application Publication No. 2002/0041847 ('847 application) or Sen et al., (J. of Hematology and Stem Research, 2001, 247-260), in view of U.S. Patent No. 7,282,222 to Phillips. The Examiner asserted that it would be obvious to one of skill in the art to substitute one type of targetable biological moiety in a bi-specific antibody with another type of targetable moiety, such as a stem cell specific moiety.

Applicants' invention, as recited in amended claim 1, provides a composition of matter which comprises an anti-c-kit X anti-VCAM1 bispecific monoclonal antibody.

The '847 publication discloses bispecific monoclonal antibodies including an anti c-kit X anti c-kit-receptor bispecific monoclonal antibody. However, the '847 publication does not disclose that one arm of the bispecific antibody binds to VCAM-1.

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Serial No.: 10/553,853
Filed: October 19, 2005
Page 5

Sen et al. disclose an anti-CD3, anti-HER2/neu bispecific antibody for use in arming activated T cells for treatment of HER2/neu⁺ tumors. Specifically, the anti-CD3 portion of the bispecific antibody binds to T-cells whereas the anti-HER2/neu portion of the antibody binds to HER2/neu⁺ cells. Nowhere does Sen et al. teach or suggest an anti-c-kit X an anti-VCAM-1 bispecific monoclonal antibody.

The '222 patent discloses delivering stem cells to a target tissue in a mammal using a glycoconjugate to traffic the cell to a desired tissue. Nowhere does the '222 patent disclose a bispecific anti-c-kit X anti-VCAM1 bispecific monoclonal antibody.

Applicants maintain the no combination of the cited references renders applicants' claimed invention obvious. Specifically, none of the references disclose a bispecific antibody which binds to VCAM-1.

Moreover, applicants' claimed composition of matter provides the unobvious and unexpected result of actually homing stem cells to diseases or injured myocardial tissue (see page 38, lines 4-7).

Applicants have also retained withdrawn claim 46 as pending claim amended to incorporate all of the limitations of amended claim 1. If claim 1 is allowed applicants maintain that they are entitled to have withdrawn claim 46 rejoined and allowed. In this regards, applicants have amended claims 9 and 11 and added new claim 92, each of which depends from claim 46. These claims should also be rejoined and allowed if claim 46 is rejoined and allowed.

In view of the amendments to the claims and the preceding remarks, applicants respectfully request that the Examiner reconsider and withdraw the ground of rejection under 35 U.S.C. §103.

Applicants: Lawrence G. Lum and Randall J. Lee
Serial No.: 10/553,853
Filed: October 19, 2005
Page 6

Obviousness-Type Double Patent Rejection

The Examiner provisionally rejected claims 1-12 under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-11 of U.S. Patent Application Serial No. 11/170,716. The Examiner noted that this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants respectfully traverse the Examiner's ground of rejection. As an initial matter, applicants note that the U.S. Serial No. 11/170,716 has is no longer a pending application, although another application, U.S. Serial No. 12/207,285, filed September 9, 2008, claims the benefit of U.S. Serial No. 11/170,716.

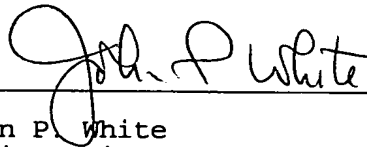
Applicants further maintain that if the claims in this application are otherwise in condition for allowances the provisional rejection should be withdrawn and the issue of obviousness type double patenting should be taken up in respect to the other pending application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants: Lawrence G. Lum and Randall J. Lee
Serial No.: 10/553,853
Filed: October 19, 2005
Page 7

No fee, other than the enclosed \$555.00 fee for a three-month extension fee is deemed necessary in connection with the filing of this Amendment. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.


Respectfully submitted,



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2/2/09
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